

## Remarks

### Specification Objections

Applicant has canceled the abstract, which was taken from the parent case, and substituted a new abstract that describes the elected invention. Applicant has also amended the title to reflect the elected invention. Applicant has amended the specification to update the status of one of the parent applications and remove the word “copending” with respect to any patented application. Applicant has also amended the specification to address other informalities identified by the Examiner in related cases. Accordingly, Applicant respectfully submits that the objections to the disclosure have been overcome.

### Double Patenting Rejections

Claims 62, 63, 71, and 76 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 70, and 74 of co-pending Application No. 10/033,515. In response and in order to expedite the prosecution of this application, Applicant submits herewith a Terminal Disclaimer to obviate this double patenting rejection. It should be understood that this Terminal Disclaimer is being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimer is necessary.

### 35 U.S.C. §102 Rejection based on Kensey

Claims 62, 63, 67, 69-71, 76, and 96 were rejected under 35 U.S.C. §102(b) as anticipated by Kensey (US Patent No. 4,890,612). For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by Kensey.

Kensey discloses a device that is used to seal an opening, e.g., a percutaneous incision or puncture. The device is a closure 20 that comprises a holding member 102, a suture or filament 104, and a sealing member 106 to seal the incision or puncture. Holding member 102 is an elongated body constructed like a toggle and can be formed of a biodegradable, thermoplastic polymer, such as polyglactide. The holding member (toggle) 102 is molded onto the distal end of the filament 104 which is slightly bulbous to hold the toggle 102 in place thereon. The filament 104 can also be formed of polyglactide. Disposed proximally behind the toggle 102 is the

sealing member 106. The sealing member 106 comprises a cylindrical plug that can be formed of a compressed foam which is highly absorbent and which, when disposed within the body, swells in excess of its compressed diameter. The plug can be formed of gelatin or collagen foam so that it also degrades quickly with the body. The filament extends fully through the plug (col. 6, lines 24-51).

In an alternative embodiment, Kensey teaches a closure 200 which comprises a preformed foam plug having an enlarged distal end portion 106 serving as the previously described holding member, a proximally located rod-like portion 102 serving as the previously described sealing member and a retraction filament 104 secured thereto. The closure 200 can be formed of a dense collagen foam with long collagen fiber reinforcement so that it has a high expansion ratio and good mechanical wet strength (col. 7, lines 34-45).

The presently claimed invention is different from Kensey. First, the presently claimed invention specifies that the first implant is positioned in tissue, passes through a second implant, and expands within the tissue. In Figure 9 of Kensey, the plug device includes a filament 104, a holding member 102, and a sealing member 106. Contrasting Kensey's elements with the first implant of the present invention, Kensey's filament 104 does not expand. Kensey's holding member 102 does not expand nor does it pass through another plug element. Nor does Kensey's sealing member 106 pass through another plug element. Nothing in Kensey suggests or teaches all the elements of the claimed first implant.

The presently claimed invention also specifies that the second implant is positioned against the tissue, and the first implant passes through the second implant which expands. Contrasting Kensey's elements (in Figure 9) with the second implant of the present invention, Kensey's filament 104 is not positioned against tissue and no other device element passes through the filament. Kensey's holding member 102 is not penetrated (nothing passes through) by another device element which expands. Nor is Kensey's sealing member 106 penetrated by another device element which expands. Nothing in Kensey's embodiments suggests or teaches all the characteristics of the first and second implants of the present invention.

Furthermore, the presently claim invention differs from Kensey's alternative embodiment shown in Figure 12. The alternative plug device includes closure 200 and a filament 104.

Contrasting Kensey's alternative plug elements with the first implant of the present invention, Kensey's closure 200 does not pass through another device element, while Kinsey's filament 104 does not expand. Furthermore, contrasting Kensey's alternative plug elements with the second implant of the present invention, Kensey's closure 200 is not penetrated by another device element. Kinsey's filament 104 is not positioned against tissue and is not penetrated by another device element. Nothing in Kensey's alternative embodiment suggests or teaches all the characteristics of the first and second implants of the present invention.

Based on the above remarks, Applicant respectfully submits that amended claim 62 is patentably distinct over Kensey. Applicant also submits that claims 63, 67, 69-71, 76, and 96 are allowable as well at least because these claims depend from claim 62.

#### 35 U.S.C. §102 Rejection based on Draenert

Claims 62, 63, 67, 69-71, 76, and 96 were rejected under 35 U.S.C. §102(e) as being anticipated by Draenert (U.S. Patent No. 5,084,050). For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by Draenert.

Draenert discloses an implant for treating bone fractures where the implant is securely anchored in the bone by screwing in a bone screw or locking a wedge, peg or bone cylinder such as a cartilage bone cylinder or a ligament bone cylinder, or by inserting, screwing in or injecting an interchangeable medication and/or radiation therapy vehicle (col. 3, lines 4-9). In other words, the implant or dowel is inserted in a first bone and a screw or other cylinder secures a second bone to the first bone.

In contrast, the presently claimed invention includes a first implant which secures a second implant to tissue. The first implant of the present invention is a unitary structure (Figures 12 and 12A). Nothing in Draenert teaches or suggests an implant having a unitary structure. Rather, Draenert's implant is a dowel and when fitted with a screw or cylinder becomes a fastener for securing two bones.

In light of the above remarks, Applicant respectfully submits that amended claim 62 is patentably distinct over Draenert. Based on at least their dependency, Applicant submits that claims 63, 67, 69-71, 76, and 96 are allowable as well.

Conclusion

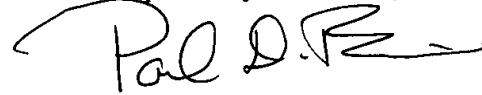
The Examiner requested a list of related co-pending applications and a copy of such co-pending claims. The following table lists the co-pending applications. Copies of the claims for these applications are attached.

Application No.	Date Filed	Attorney Docket
09/871,936	Jun 1, 2001	780-A02-006-1
09/443,906	Nov 19, 1999	780-A02-006-6
10/033,515	Oct 19, 2001	780-A02-006-10
09/988,954	Dec 11, 2001	780-A02-006-12
10/279,402	Oct 24, 2002	780-A02-006-13
10/279,451	Oct 24, 2002	780-A02-006-14
10/372,065	Feb 21, 2003	780-A02-006-15
10/371,265	Feb 21, 2003	780-A02-006-16

In light of the foregoing, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$290.00 is believed to be due for one terminal disclaimer, an Information Disclosure Statement, and an extension for response within the first month (at small entity rate) is believed to be due with this submission and a Fee Transmittal Sheet including this fee is submitted concurrently herewith. Please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-006-11).

Respectfully submitted,



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Enclosures